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A request for correction of table 1 of the description and claim 1 has been filed pursuant to Rule 88 EPC. A decision on the request will be taken during the proceedings before the Examining Division (Guidelines for Examination in the EPO, A-V, 2.2).

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(54) Radiopaque non-kinking thin-walled introducer sheath.

(57) A non-kinking introducer sheath (10) for introducing and guiding catheters into an artery or other similar vessel in the body is described. The sheath comprises an internal helical metal coil (12) fabricated from flat wire, and located within a thin plastic covering (20).

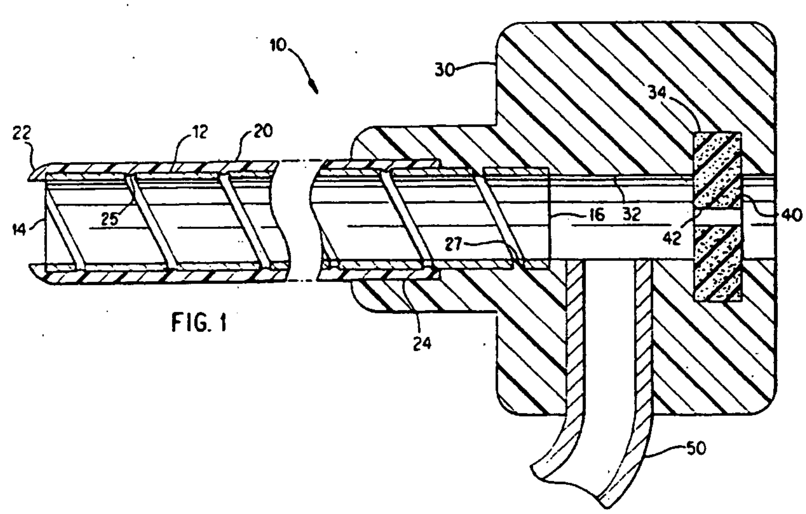

FIG. 1

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This invention relates to introducer sheaths that are inserted through the skin into an artery or oth r vessel in a living body for the purpose of subsequent percutaneous insertion and guidance of a transluminal catheter.

It is common practice in the fields of angioplasty and atherectomy to insert catheters into the artery through a plastic sheath. These sheaths are typically made from PVC or an equivalent plastic and typically have a wall thickness of 0.254mm (10 mils) it being highly advantageous to have those sh aths as thin-walled as possible. The inner diameter of such sheaths is determined by the diameter of the catheter to be placed through it, so that in order to provide that 0.254mm thickness the external diameter of the sheath is typically 0.508mm (20 mils) greater than the inside diameter. However, it would be highly advantageous to reduce the outside diameter of the sheath so as to minimise arterial distention, thereby reducing the bleeding that occurs at the insertion side after the catheter and sheath are removed from the artery, but against that significant problems do arise from the tendency of extremely thin-walled sheaths to kink or bend at the point of entry into, for example, the femoral artery or where they pass through a highly curved section of an iliac artery. Also because they are made from plastics materials, the current thin-walled sheaths are not significantly radiopaque.

The present invention to eliminate the shortcomings of the prior art devices in order to provide a radiopaque sheath that is non-kinking and with a thinner wall as compared with sheaths that are currently available. This is achieved by inserting into the sheath a helical metal coil preferably fabricated from flat wire or by utilising as the sheath such a helical metal coil covered or coated with a thin plastic covering. This may be provided by means of a plastic material coated onto and between the turns of the metal coil or by using a length of heat shrinkable tubing, or by moulding or extruding plastic over the thin helical metal coil. At the proximal end of the sheath is an adapter (hemostasis valve) through which the catheter may subsequently be placed. This adapter would typically be moulded from a plastic so as to both join onto the metal coil as well as mould onto the plastic covering of the metal coil. At its distal end, the sheath would advantageously combine a metal portion for radiopacity and at its extreme end a soft plastic tapered end piece.

The invention will be further described by reference to the accompanying drawings, in which:

Fig. 1 is a cross-sectional view of a non-kinking, thin-walled sheath according to this invention and comprising single helical metal coil having a plastics covering and with plastic extensions between adjacent turns.

Fig. 2A shows a wall section of the sheath with a plastic extension incompletely filling the space between adjacent turns.

Fig. 2B shows a wall section of a sheath where the spaces between the adjacent turns of the coil are completed filled.

Fig. 2C shows a wall section of a sheath where the spaces between the adjacent turns of the coil are almost filled.

Fig. 3A shows a wall section of a sheath wherein the flat wire has rounded ends and is considerably thinner than the plastic covering and there is a greater spacing between adjacent turns.

Fig. 3B shows a wall section of a sheath wherein there is an extension of the plastic covering between adjacent turns even though the adjacent turns are touching and the flat wire is chamfered on all corners.

Fig. 3C shows a wall section of a sheath wherein only the inner corners of the flat wire metal coil are rounded.

Fig. 3D shows a wall section of a sheath wherein only the inner corners of the flat wire metal coil are chamfered.

Fig. 3 is a longitudinal cross section of the distal end of the sheath illustrating a metal tip.

Fig. 4 is a longitudinal cross section of the distal end of the sheath illustrating a metal tip.

Fig. 5 is a longitudinal cross section of the distal ends of the sheath illustrating a metal insert near the sheath's distal end and a soft plastic tip and a very thin-walled, interior tube having lubricious coating on its interior surface.

Fig. 6 is a cross-sectional view of the distal end of a non-kinking sheath which has two helical metal coils with a plastic extension into the space between adjacent turns of the outer coil.

Referring first to Fig. 1, a non-kinking, thin-walled sheath 10 is shown with an inner metal coil 12 that lies within a plastic covering 20 for most of the length of the sheath with a plastic adapter 30 moulded onto the proximal end of the sheath 10. The metal coil 12 would typically be fabricated from flat stainless steel wire or an equivalent springy metal. Metals such as 300 or 400 series stainless steel, nickel alloys such as Monel metal, or Inconel or beryllium copper, tantalum or gold alloys could be used for the flat wire metal helix material. The thickness of the wire would typically be in the range 0.0254 to 0.127mm (1 and 5 mils) and the width of the wire would typically be between 3 to 80 times the wire thickness. This ratio of wire

width to wire thickness is a very important consideration in the design of the sheath in order to prevent the sheath from collapsing while still providing a very thin wall. By actually building a model of this sh ath, it has been determined that for the most desirable wire thicknesses which provide a very thin wall while preventing the sheath from collapsing in normal handling, only certain ranges of wire width to wire thickness are reasonable and these ratios are presented in Table 1. This table clearly shows greater width-to-thickness ratios are required as the wire thickness is decreased.

Table 1

Acceptable Wire Width-To-Thickness Ratios As a Function of Wire Thickness	
THICKNESS RANGE mm(mils)	**WIDTH-TO-THICKNESS RATIO**
0.0635 to 0.0880 (2.50 to 3.50)	3 : 20
0.0381 to 0.0632 (1.50 to 2.49)	5 : 50
0.0190 to 0.0378 (0.75 to 1.49)	12 : 80

The flat wire helix would typically be wound on a mandrel in a similar manner to the way that spring wire guides are made at the present time. Another method to form the flat wire helix would be by using machines than form tension or compression coil springs. The inner diameter of the helical coil would typically lie in the range 1.016 to 5.08mm to 200 mils) depending on the size of the catheter that has to be inserted through it. The distal end 14 and the proximal end 16 of the coil 12 would be typically cut off square as shown in Fig. 1.

Covering the helical coil 12 would be a plastic covering 20 having a thickness in the 0.0254 to 0.203mm range (1 to 8 mils) and which would typically be made from polyethylene, polyurethane, PVC, Surlyn or a similar plastic material. One method for forming the covering 20 so that it fits tightly around the helical coil 12 would be by sliding the coil 12 through a tube of the plastic and then heat shrinking the plastic onto the helical coil 12. Another method would be to dip coat the coil 12 into a liquid plastic material that hardens onto the helical coil 12 after dipping. Another method would be to overextrude plastic over the coil 12. A polytetrafluoroethylene (Teflon: Registered Trade Mark) mandrel could be inserted inside the metal coil 12 before dip coating or overextruding. Whatever method is used to form the plastic covering 20, the plastic material could have a partially filled extension 25 or a fully filled extension 27 each of which projects into the space between adjacent turns thereby preventing unwanted longitudinal displacement of one turn relative to another when the sheath 10 is severely bent. The inside diameter of either extension 25 or 27 is smaller than the outside diameter of the metal coil 12 and larger than or equal to the inside diameter of the metal coil 12.

Figs. 2A, 2B, 2C and 2D show four sheath wall sections having four different types of plastic extensions that keep adjacent turns of coils separated from each other.

Fig. 2A is an enlarged view of the wall section of the sheath shown in Fig. 1 which has a partially filled extension 25 protruding from the plastic covering 20 which extension only slightly fills the space between adjacent turns. However, the sharp corners of the metal coil 12 prevents unwanted longitudinal displacement of the turns of the coil when the sheath is bent. This form of plastic extension is typical of that which would be obtained with heat shrinkable tubing followed by centreless grinding of the outer surface of the covering 20.

Fig. 2B shows a completely filled extension 27 of the plastic covering 20 which design is also shown in Fig. 1. This shape would typically be obtained when the plastic covering 20 is overextruded with a right fitting cylindrical mandrel (typically made from a polytetrafluoroethylene cylinder) placed inside the metal coil 12. The tight fitting mandrel (not shown) prevents plastic from adhering to the inner surface of the metal which, if it should occur, would result in an undesired increased wall thickness of the sheath. This type of projection could also be obtained by placing a liquid plastic material between the turns of a metal coil that has been wound on a mandrel and then placing an outer plastic covering 20 over the metal coil 12. An importance of this design is that the sharp inner corners of the flat are covered.

Fig. 2C shows a mostly filled extension 26 which could be formed by placing a hollow polytetrafluoroethylene (Teflon) tube (not shown) inside the metal coil and then inflating the tube and then overextruding the plastic covering 20 onto and in between the coil 12. The tube would be deflated to allow it to be withdrawn. An importance of this design (like Fig. 2B) is that the sharp inner corners of this flat wire are covered.

Fig. 2D shows an over-filled extension 28 which could be formed by using h at shrinkable tubing for the plastic covering 20 and then heating the metal coil 12 until the metal coils "m lt" into that plastic covering 20. It is also possible to overextrude the plastic covering 20 and with the appropriate type of plastic, pressure and temperature to form the plastic shape as shown in Fig. 2D. This design cov rs the inn r corners of the flat wire and furthermore, an inner lubricity coating could be applied to the plastic to allow easier passage for an inserted catheter.

Figs. 3A, 3B, 3C and 3D illustrate four other embodiments of wall sections for a non-kinking sheath. Fig. 3A shows an embodiment in which the flat wire metal coil 33 has a wire thickness that is considerably smaller than the thickness of the plastic covering 20. Furthermore, the coils 33 have inner and outer rounded edges. This particular wall section is shown with a plastic extension 27 similar to that shown in Fig. 2B. The width of each turn of the coil 33 is L1, and the length of the separation between turns is L2. In Fig. 3A, L2 is greater than L1. Typically L2 would be equal to or less than L1. However, if greater flexibility is desired, L2 can be several times greater than L1. However, if L2 is greater than 1 to 2 cm, then the sheath might no longer be non-kinking. It should also be understood that a sheath might use a variable spacing L2 between adjacent turns. For example, L2 might be 0.5mm for most of the sheath's length but L2 might be gradually increased to 5mm at the sheath's distal end in order to increase the flexibility of the sheath's distal end.

Fig. 3B shows a wall construction in which adjacent turns are touching. However, the ends of the coils 35 are shaped so that a plastic extension 29 of the plastic covering 20 extends into the space between adjacent touching turns.

Figs. 3C and 3D show an embodiment of the coils 37 and 39 in which there is a generally squared off outer corner at the end of each turn and a generally rounded inner corner at the end of each turn. Specifically, in Fig. 3C the inner corners of the coil 37 are rounded and in Fig. 3D the inner corners of the turn 39 are chamfered. It should also be understood that the outer surface of the coil could be finished so as to prevent adhesion of the plastic covering 20 to the coil; or conversely, the outer surface of the coil could be treated to cause the metal coil to bond to the plastic covering 20. Generally, adhesion or bonding of the coils outer surface to the plastic covering 20 will result in a less flexible sheath. Furthermore, increasing the ratio of L2/L1 (as seen in Fig. 3A) will increase sheath flexibility. It is well known in the wire forming art that any of the wire shapes showing in Fig. 3 could be obtained by slitting, drawing or extruding the flat wire through a die; or a combination of these methods could be used to form the desired cross section of the generally flat wire. The cross section of Fig. 3A could also be obtained by rolling down round wire.

The shapes shown in Figs. 3C and 3D are advantageous in that their sharp outside corners dig into the plastic covering 20 thus preventing unwanted longitudinal displacement of the turns of the coil when the sheath is severely bent. Furthermore, the rounding or chamfering of the inside edge prevents the outer surface of a tight fitting catheter from being damaged by exposed sharp inner corners such as those shown in Fig. 2A as a tight fitting catheter is pushed through the sheath. Also, a tight fitting catheter would slide through the inside of the sheath with less friction or catching (especially through bends in the sheath) if the inside corners of the metal coil are rounded or chamfered as shown in Figs. 3C and 3D.

It also envisioned that any of the flat wire metal coil designs described herein could be coated with a metal or plastic so as to enhance the sheath's radiopacity or to decrease frictional forces on any catheter that would be placed through the sheath. For example, gold or tantalum plating of the flat wire would enhance the sheath's radiopacity. Furthermore, the metal coil could have a lubricity coating applied to decrease frictional forces of objects passing the sheath's interior lumen. Additionally, the bare metal could be given a thin plastic coating which would then have a lubricity coating applied. Further, there could be a very thin, separate plastic cylinder inside the metal coil. Further, as to coatings, a lubricity coating could be applied to the sheath's exterior plastic covering 20 to allow the sheath to enter human tissue and advance through human blood vessels while minimising frictional resistance. The outer surface of the plastic covering 20 could also be treated with an anti-bacterial coating which would be especially important for sheaths that remain in a vessel for more than a few hours. Still further, the exterior plastic covering 20 could be centreless ground to make a smoother outer surface of the sheath.

In Fig. 1 we see that the distal tip 22 of the plastic covering 20 might be heat moulded to an appropriate shape which can readily pass through the arterial wall with the aid of a dilator (not shown). The proximal end 24 of the covering 20 would have moulded onto it a plastic adapter 30 (typically including a hemostasis valve) which can have a side-port 50 as shown in Fig. 1. The adapter 30, which may be formed from the same plastic material as the covering 20 or from another material such as PVC, would also be moulded onto the proximal end of the helical coil 12. The adapter 30 would have an interior cylindrical hole 32 whose inside diameter is moulded to match the inside diameter of the helical coil 12. A cylindrical

groove 34 would be moulded into the adapter 30 so as to accept a foam rubb r packing gland or hemostasis valve 40. The packing gland 40 has a hole 42 through its centre to allow for the passage of a catheter. The purpose of the gland 40 is to seal around the outside diameter of the catheter when it is in place to prevent arterial blood from escaping between the inner cylinder 32 of the adapter 30 and the outside diameter of the catheter that is percutaneously placed into the arterial system. The packing gland 40 is only indicative of more sophisticated hemostasis valves that would be used with such a sheath. An example of such a valve is shown in U.S. Patent No. 5,041,095 by P.K. Littrell entitled "Hemostasis Valve".

As previously described, the strip of metal forming the helical coil 12 would have a thickness in the range o.0254 to 0.127mm (1 to 5 mils). Similarly the plastic covering 20 would typically have a thickness in the same range to that the total thickness of the coil 12 and covering 20 would be in the range 0.0508 to 0.254mm (2 to 10 mils). At 0.254mm thickness, the sheath would have the advantage of being non-kinking and radiopaque. However, it would not have any advantage in reducing the outer diameter of the sheath 10 as compared to other sheaths that are currently available. However, as we approach wire and plastic covering thicknesses the order of 0.0508mm (2 mils), the outer diameter of the sheath 10 is significantly reduced. There is a distinct advantage in dramatically reducing the wall thickness of the sheath 10 while at the same time having improved resistance to kinking which is provided by the strength of the helical coil 12.

Fig. 4 illustrates an improved tip design for this type of thin-walled sheath 10. As typical for this sheath design, the metal coil 12 is encased in a plastic covering 20. A metal tip 60 is joined to the coil 12 and/or covering 20 by adhesive bonding, welding or brazing or an equivalent joining means. Although a stainless steel tip could be used, a dense metal such as gold or tantalum (or an alloy of these metals) would have the advantage of greater radiopacity.

Fig. 5 illustrates the distal end of a sheath 10 with a metal insert 62 joined to the coil 12 and plastic covering 20. The design of Fig. 5 would be similar to that of Fig. 4 except that a plastic tip 64 extends beyond the metal insert 62. Furthermore, the inside diameter of the insert 62 could be smaller than the inside diameter of the coil 12; and the inside diameter 66 of the plastic tip 64 could be still smaller. This design would provide a tighter fit around the dilator for improved insertion of the sheath into a vessel. Further, the soft plastic tip is potentially less damaging to the soft tissue into which the sheath plus dilator would be inserted.

Fig. 5 also shows a separate very thin-walled, plastic tube (or coating) 68 which could be placed interior to the sheath to improve lubricity. Such a tube could be advantageously made from polytetrafluoroethylene or a different plastic with an interior surface coating to improve lubricity. Such an interior tube could be used with any tip design of the sheath. Fig. 5 also shows a separate plastic spacer 69 that lies between adjacent turns of the metal coil 12 and between the inner plastic tube 68 and the outer plastic tube 20. Thus, if desired, as many as three different plastic materials can be used for elements 20, 68 and 69 in order to optimise the properties of these three different parts of the sheath.

Although Fig. 1 shows only a single coil 12, it is envisioned that the helical coil 12 might be made from two separate metal coils, one inside the other, that are wound in opposite directions (as shown in Fig. 6) so as to improve the strength of the sheath. Fig. 6 shows the distal end of a two coil sheath 11 which has an inner helical metal coil 17, an outer helical metal coil 13, both of which are finished with a straight distal end 15. Fig. 6 also shows a plastic covering 21 with a moulded distal end 23 which design is similar to Fig. 1. A Fig. 6 type design in which the inner metal coil is nominally 0.0508mm (2 mils) thick, the outer metal coil is nominally 0.0508mm (2 mils) thick and the plastic covering is also 0.0508mm (2 mils), would achieve a non-kinking sheath design which still has a significant wall thickness reduction as compared to sheaths that are currently available.

All the sheaths designs described herein have metal coils which are intrinsically radiopaque. Hence these sheath designs have the additional functional attribute of being radiopaque even without the addition of highly radiopaque distal tips.

The possibility of a very thin plastic coating or plastic tube on the interior surface of the inside metal coil is also envisioned for these sheath designs as shown in Fig. 5. Such a coating or plastic tube would optimally have a very low coefficient of friction.

Although the utilisation of sheaths in arteries is described herein in considerable detail, the sheath that is taught herein is also able to be used for access to a variety of lumens of humans or animals, such as veins, urethras, fallopian tubes, biliary ducts, bronchial tubes or any similar vessel in a living body.

Various other modifications, adaptions, and alternative designs are of course possible in light of the above teachings without departing from the scope of the appended claims.

Claims

1. An introducer sheath (10) for percutaneous insertion into a vessel of a human body and when so inserted serving as a guide for the subsequent insertion of a catheter into said vessel and having an adapter (30) including a hemostasis valve (40) located at one end of the sheath for inserting guide wires and/or catheters through the sheath and into the said vessel, characterised in that the introducer sleeve (10) comprises a wire metal coil (12) constructed from flat wire strip forming the interior wall of the sheath and coated or covered with a plastic covering (20) that is fitted onto and is in contact with the exterior surface of said metal coil.

2. An introducer sleeve according to claim 1, characterised in that the material of said plastic covering (20) projects at least partially into spaces between adjacent turns of the metal coil but without covering the interior surface of the metal coil.

3. An introducer sheath according to claim 1 or 2 characterised in that the metal coil (12) is made from stainless steel, preferably either a 300 series stainless steel or a 400 series stainless steel.

4. An introducer sheath according to claim 1, 2 or 3, characterised in that the flat wire of the metal coil has a thickness in the range 0.635 to 0.889mm (2.5 to 3.5 mils) and a width to thickness ratio to the range 3:1 to 20:1, or a thickness in the range 0.381 to 0.632mm (1.50 to 2.49 mils) and a width to thickness ratio in the range 5:1 to 20:1, or a thickness in the range 0.019 to 0.378mm (0.75 to 1.49 mils) and a width-to-thickness ratio in the range 12:1 to 80:1.

5. An introducer sheath according to any one of claims 1 to 4, characterised in that the metal coil (12) has spaces between adjacent turns that are each less than the width of a single turn of the coil.

6. An introducer according to any one of claims 1 to 4, characterised in that the metal coil (12) has spaces between adjacent turns that are larger than the width of a single turn of the coil.

7. An introducer sheath according to claim 5 or 6 characterised in that the spaces between adjacent turns are all of the same dimension.

8. An introducer sheath according to claim 5 or 6 characterised in that the spaces between adjacent turns vary in dimension along the length of the coil, the spaces between adjacent turns at the sheath's distal end preferably being greater than those at the proximal end adjacent said adapter (30).

9. A sheath according to any one of claims 1 to 4, characterised in that the helical coil (12) is formed from that metal strip having chamfered or rounded edges.

10. A sheath according to claim 9, characterised in that the chamfered or rounded edges of the wire strip in each turn are substantially contiguous with those of the adjacent turns.

11. An introducer sheath according to any one of claims 1 to 10, characterised in that the metal coil (17) is plated with a dense radiopaque metal preferably gold or tantalum.

12. An introducer sheath according to any one of claims 1 to 11, characterised in that the internal surface of the metal coil is provided with a lubricious coating.

13. An introducer sheath according to any one of the preceding claims characterised in that the outer covering of the sheath is formed by a preformed plastics sleeve, heat shrunk onto the metal coil.

14. An introducer sheath according to any one of the preceding claims characterised in that the thickness of the plastic covering is in the range 0.0254 to 0.203mm (0.001 and 0.008 inches).

15. An introducer sheath according to any one of the preceding claims characterised in that the plastic covering is centreless ground on its exterior surface to provide a smooth finish on that exterior surface.

16. An introducer sheath according to any one of the preceding claims characterised in that the plastic covering has a lubricated ext rnal surface.

17. An introducer sheath according to any one of the preceding claims characterised in that the sh ath has a metal tip (60) or insert (62) at the end.

18. An introducer sheath according to claim 17, characterised in that the metal tip (60) consists of or comprises a high density radiopaque metal, preferably tantalum or gold.

19. An introducer sheath according to any one of the preceding claims, characterised in that the sheath has a thin plastics liner (68) located internally of the helical coil (12).

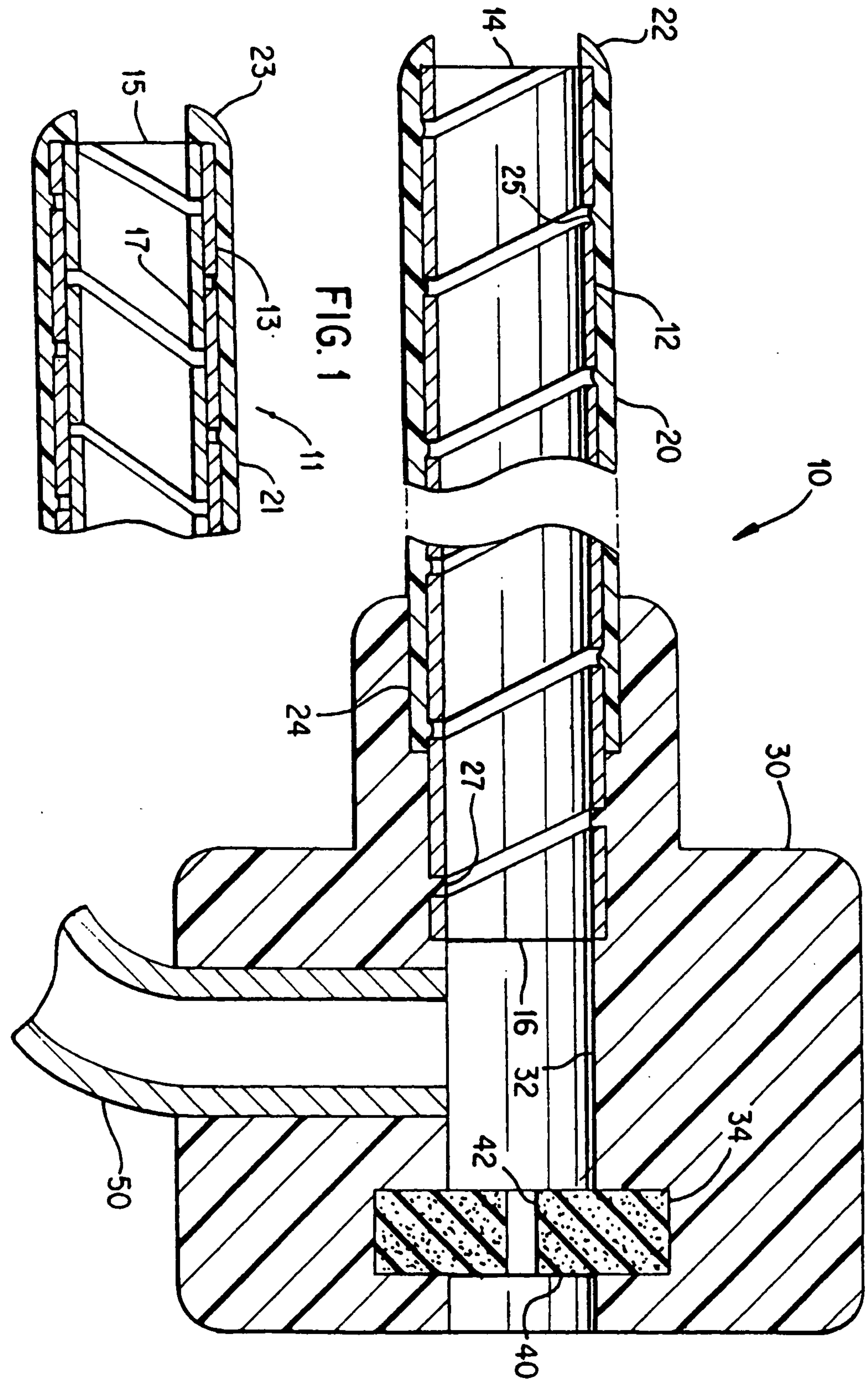
FIG. 1
FIG. 6
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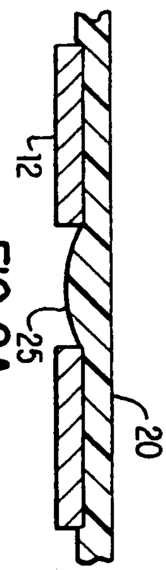

FIG. 2A

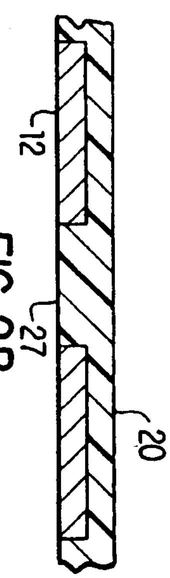

FIG. 2B

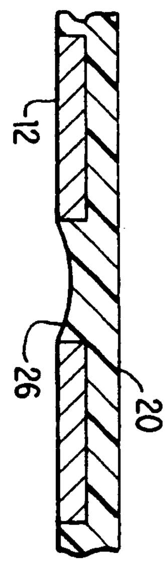

FIG. 2C

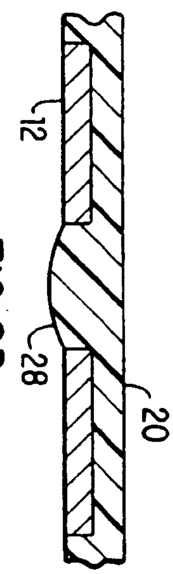

FIG. 2D

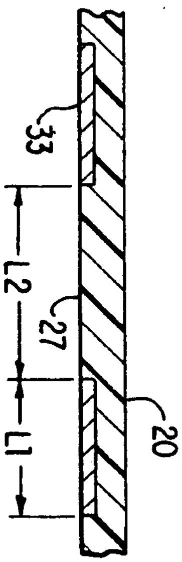

FIG. 3A

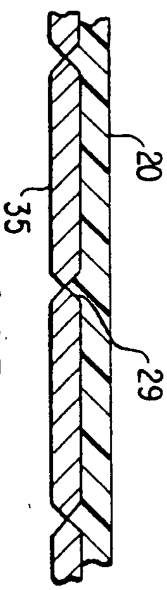

FIG. 3B

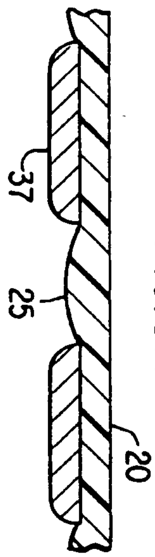

FIG. 3C

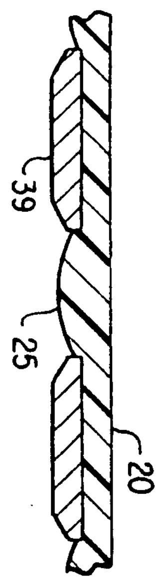

FIG. 3D

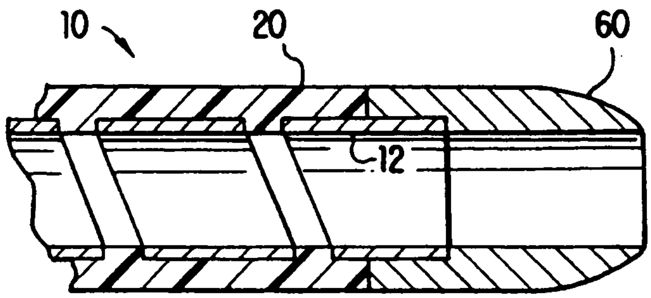

FIG. 4

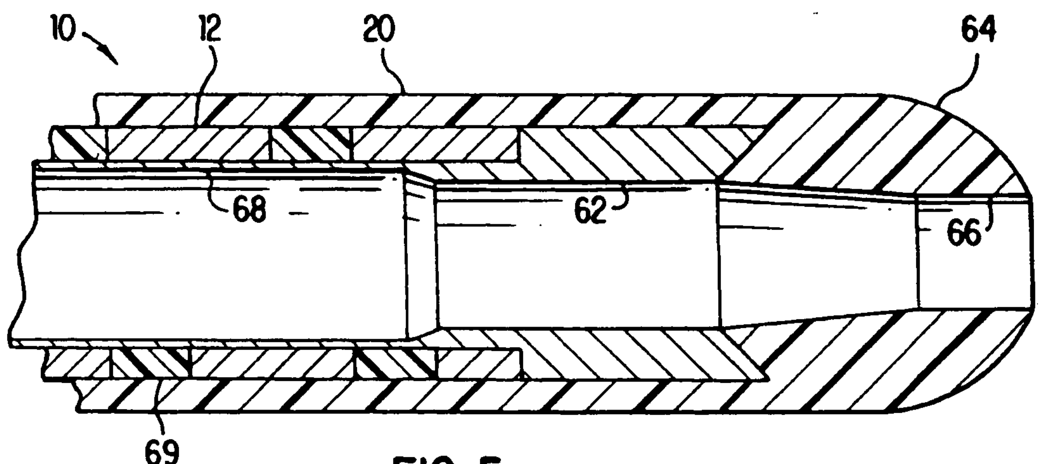

FIG. 5